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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,246	02/08/2000	Todd P. Foster	6231.N-CN1	2305
7590	04/21/2004		EXAMINER CHOI, FRANK I	
Andrew M Solomon Pharmacia & Upjohn Company Global Intellectual Property 301 Henrietta Street Kalamazoo, MI 49001			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 04/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/500,246	<b>Applicant(s)</b> FOSTER ET AL.	
	<b>Examiner</b> Frank I Choi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-28, 32-38 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-28, 32-38 and 42-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101/112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28, 32,33, 36, 38, 42-47 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 26, 28, 32,33, 36, 38, 42-47 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Amendment (1/20/2004). In that paper, applicant has stated the invention is the form of tablet(s) or pellet(s), and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not require that the inplant, first component or second component are in the form of tablet(s) or pellet(s), i.e. the first component can be a porous or freeze-dried solid composition and the second component can be biodegradable solid substances, conventional tablet/pellet ingredients (does not require that the second component actually be in the form of a pellet or tablet only that it contain ingredients which are conventionally found in pellets/tablets), or matrix-type systems.

Claims 34,35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 35 claim a product and process in the same claim, i.e. that the implant composition is implanted in an animal body by injection. A single claim which claims both a

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product and the method steps of using the product is indefinite under 35 U.S.C. 112, second paragraph. Said claims are also rejected under 35 U.S.C. 101 as the claims are directed to neither a “process” nor a “composition,” but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP Section 2173.05(p)(II). Examiner suggests the phrase “wherein said implant composition is capable of being implanted in an animal body by injection”.

Claim 34 recites the limitation "biologically active composition". There is insufficient antecedent basis for this limitation in the claim. Examiner suggest that “said melengestrol acetate” be used.

#### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28, 32-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carr et al. (US Pat. 5,227,167).

Carr et al. expressly disclose a dispensing device containing a second beneficial agent containing Multiwax <sup>TM</sup> and melengestrol acetate and a first beneficial agent formulation (loading dose) in the containing melengestrol acetate, sodium alginate or polyethylene oxide, microfine wax, hydroxypropylmethylcellulose, magnesium stearate in the form of a tablet falling within the scope of applicant's claims (Columns 12-14).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 26-28, 32-38, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US Pat. 5,227,167) in view of Babcock et al. (US Pat. 3,417,182), Montgomery et al., and Grimm (US Pat. 5,522,797).

Carr et al. disclose a dispensing device containing a second beneficial agent containing Multiwax <sup>TM</sup> and melengestrol acetate and a first beneficial agent formulation (loading dose) in the containing melengestrol acetate, sodium alginate or polyethylene oxide, microfine wax, hydroxypropylmethylcellulose, magnesium stearate in the form of a tablet (Columns 12-14). It is disclosed that the device is can be used as a subcutaneous implant, can be administered singly or several at a time to humans or animals, can contain two or more hormones and that the first and second beneficial agent formulations can contain the same beneficial agent(s) (Column 6, lines 18-28, 46-68, Column 7, lines 1-5). It is taught that the first beneficial agent formulation can be provided in the form of a tablet or capsule and can be round, spheroid, toroid, cylindrical, square and the like (Column 7, lines 62-68). It is taught that the second beneficial agent

formulation may be liquid, semi-solid or thermoresponsive such as that set forth in US Pat. 4,772,474, the disclosure of which is incorporated by reference (Column 8, lines 39-51). It is disclosed that thermoresponsive compounds include hydrophobic and lipophilic carriers as well as hydrophilic and water miscible carriers, such as fats, oils, waxes, fatty acid esters, polymers of polyalkyleneglycol, block polymers, which thermoresponsive compounds are preferably solid at temperatures up 24 degrees Celcius (See US Pat. 4,772,474, Column 15, lines 45-68, Column 16, Column 17, lines 1-14). It is taught that the device provides rapid delivery to the environment of use of the beneficial agent together with continuous and prolonged delivery of the agent, substantially eliminating the start of time associated with prior art devices (Column 3, lines 48-54, Column 4 lines 13-23).

Babcock et al. teach that melengesterol acetate is injectable and implantable and useful in the veterinary field for control of estrual periods and stimulation of growth (See entire document, especially Abstract, Column 1, lines 41-45).

Montgomery et al. disclose that melengesterol acetate, trenbolone acetate and estradiol can be used together and that anabolic implants have been used as a production tool by cattle feeders for several decades (See entire reference, especially pages 1 and 4).

Grimm discloses a veterinary implanter for injecting a plurality of pellet doses, including approve growth hormones, into the hide, skin or ears of an animal, such as cattle (Column 1, lines 5-14, 60-68, Column 4, lines 1-45). It is disclosed that the implanter avoids the problems of prior art implanters, failing to leave the pellets in the ear when withdrawing the needle or forgetting to advance the pellet magazine, by automatically advancing the pellet magazine and ejecting the pellets from the needle (Columns 1, 2).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an implant composition consisting essentially of a first component comprising pellets of melengestrol acetate with disintegrating agent capable of immediately releasing the melengestrol and a second component comprising pellets of melengestrol acetate not containing a disintegrating agent which is capable of releasing on a sustained basis said melengestrol suitable for administration by a single injection consisting essentially of one to four pellets of the first component and four to six pellets of type the second component and a method of delivering an implant containing the first claimed component and the second claimed component by injecting the inplant into the animal body. However, the prior art amply suggests the same as the prior art discloses implants containing hormones such as melengestrol acetate, trenbolone acetate and estradiol for increasing growth in animals, that said hormones can be used together and that hormone implants, such as pellets, can be injected into animals, and implants with and without disintegrating agents, in the form of tablets or pellets, containing polymers, waxes, oils, fats or fatty acid esters, and that a plurality of inplants may be administered, and implants containing a first component in containing melengestrol acetate and disintegrating agent in a tablet for immediate release and melengestrol acetate without a disintegrating agent in a tablet for sustained release. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation of increasing the growth of animals by injecting a plurality of devices as an inplant into the body of the animal, such as in the ear, which avoids a slow start up time by use of an immediately releasing component in combination with a sustained releasing component.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 26-28, 32-38, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Pat. 5,288,496) in view of Herbert et al. (U.S. Pat. 5,654,008) and Okada et al. (4,652,441) for the reasons of record set forth in the prior Office Actions in further view of Babcock et al. (US Pat. 3,417,182) and Montgomery et al. and the further reasons below.

Lewis, Herbert et al. and Okada et al. were discussed in the prior Office Actions and the same are incorporated herein.

Babcock et al. and Montgomery et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the prior art relate to microparticles whereas Applicant's methods for preparing the drug preparing the immediate-release component are related to tablets, granules or pellets. Applicant references methods of forming granules or pellets which are disclosed in the Specification. However, the claims do not set forth said methods of preparation and do not set forth a minimum size for tablets, granules or pellets or indicate that the same do not include microparticles. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the process in which the pellets, granules or tablets are prepared) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26



USPQ2d 1057 (Fed. Cir. 1993). In any case, as indicated in the 35 USC 112 2<sup>nd</sup> paragraph rejection above, Applicant's claims, other than claims 27, 34,35, 37, do not require that the first component or second component be in the form of a pellet(s) or tablet(s). Further, as defined in Merriam-Webster's Collegiate Dictionary (10<sup>th</sup> Ed. 1998) at pages 508,857 and 1199, respectively, the definition of "granule" includes "a small particle," the definition of "pellet" includes "a usu. small rounded, spherical, or cylindrical body (as of food or medicine)" and the definition of "tablet" includes "a small mass of medicated material." A microparticle containing melengestrol acetate would appear to constitute a small particle, a small mass of medicated material as well as small rounded or spherical body of medicine.

Applicant argues that melengestrol is different from melengestrol acetate, however, Applicant does not show that melengestrol acetate would not be obvious to one of ordinary skill in light of the prior art. Clearly, one of ordinary skill in the art would envisage the use of pharmaceutically acceptable salts of melengestrol. For instance, Herbert et al. discloses the use of megestrol acetate and uses the phrase "and the like" to modify melengestrol (Herbert et al., Column 17, lines 55-63). As such, one of ordinary skill in the art would expect that melengestrol acetate would be suitable. Notwithstanding the same, Examiner cites to Babcock et al. as further evidence that one of ordinary skill in the art would readily recognize that melengestrol acetate would be a suitable form of melengestrol would be motivated to use melengestrol acetate as it is effective in controlling estrual and promoting growth in animals.

Applicant argues that the Herbert et al. composition probably does not have release rates for each of the peaks. However, Applicant presents no evidence that Herbert et al. does not have an immediate release. Neither the fact that a smooth curve could be drawn through the data nor

Applicant's speculation as to the cause of the variability constitutes evidence that there is no immediate release.

Applicant argues that there is no suggestion in the references of the desirability of combining the references, however, the motivation to combine or modify the references was set forth in the prior Office Actions and above and the same is incorporated herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 26-30, 33, 36-40, 43-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US Pat. 5,874,098). Examiner withdraws the rejection solely because Stevens et al. does not disclose the use of melengesterol.

Claims 26, 32,33, 36, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickey et al. (US Pat. 5,792,477) for the reasons of record set forth in the prior Office Actions in further view of Babcock et al. and Montgomery et al. and the further reasons below.

Rickey et al. was discussed in the prior Office Actions and the same is incorporated herein.

Babcock et al. and Montgomery et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons similar to above, i.e. that Applicant claims, other than as indicated above, do not require that component one and two be in the form of pellets or tablets, that the term tablet or pellet does not exclude microparticles and the use of melengestrol acetate would be obvious to

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one of ordinary skill in the art (Rickey et al. at Column 13, lines 19-27 discloses the same material as set forth in Herbert et al. at column 17, lines 55-63).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

April 14, 2004



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600